



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/889,379 | 07/16/2001 | Hiroshi Sugiyama | 56212 (71526) | 2742 |

21874 7590 07/03/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 07/03/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/889,379

Applicant(s)

Sugiyama et al.

Examiner

Joyce Tung

Art Unit

1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 15, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-13, 18, 19, and 22-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 12, 18, 19, and 22-26 is/are rejected.
- 7) ☒ Claim(s) 13 and 27 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1637

DETAILED ACTION

1. The amendment filed 4/15/2003 has been entered. Following the entry of the amendment, claims 1-6, 11-13, 18-19 and 22-27 are pending.

Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Applicant's arguments with respect to claims 1-6, 11-13 and 18-19 have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUNDS OF REJECTIONS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, and 11-12, are rejected under 35 U.S.C. 102(b) as being anticipated by Asai et al. (J. Am. Chem. Soc. 1994, vol. 116, pg. 4171-4177).

Asai et al. disclose a novel property of Duocarmycin and its analogues for covalent reaction with DNA. The chemical compound contains a pyrrole or imidazole derivatives and a

Art Unit: 1637

chemical structure comprising a cyclopropane ring (See pg. 4174, the Abstract and fig. 1). The teachings of Asai et al. anticipate the limitations of 1, 6, and 11-12.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-5, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asai et al. (J. Am. Chem. Soc. 1994, vol. 116, pg. 4171-4177) as applied to claims 1, 6, and 11-12 above, and further in view of Wang et al. (5,843,937).

Art Unit: 1637

The teachings of Asai et al. are set forth in section 3 above. Asai et al. do not disclose duocarmycin and its analogues applied to cancer patient or cells containing DNA or RNA, measuring the effect of survival or death of the cell by coloring the cells.

Wang et al. disclose DNA alkylating agents which are useful antitumor agents and were tested for cytotoxicity to cancer cells (See column 26, lines 29-43). The cancer cells and the drugs were added to the plate (See column 26, lines 29-43).

One of ordinary skill in the art at the time of the invention was made would have been motivated to apply duocarmycin or its analogues to a multi-well plate with tumor cells in order to detect an action of duocarmycin or its analogues to a substance containing DNA or RNA. Wang et al. disclose antitumor drug which is tested by using multi-well plate to indicate the drug is useful and is high potency compounds for cancer cells over normal tissue (See column 1, lines 53-58). It would have been prima facie obvious to apply the multi-well plate of Wang to apply duocarmycin or its analogues with tumor cells in order to detect an action of duocarmycin or its analogues to a substance containing DNA or RNA⁶ Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asai et al. (J. Am. Chem. Soc. 1994, vol. 116, pg. 4171-4177).

The teachings of et al. are set forth in section 3 above and Asai et al. do not disclose a kit containing the compound for performing the method. However, it would have been prima facie obvious to construct a kit with the reagents needed for perform a method because it was well

Art Unit: 1637

known in the art at the time of instant invention to construct the kit for the convenience of performing the method.

Allowable Subject Matter

7. Claims 13 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

No prior art has been found teaching or suggesting the compound listed in claims 13 and 27 used to detect an action to a substance containing DNA or RNA.

Summary

9. No claims are allowable.

10. The references of Boger et al., Sugiyama et al., and Eis et al. are made of record as references of interests because this references disclose duocarmycin and its analogues.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1637

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12 Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in

Application/Control Number: 09/889,379


Page 7

Art Unit: 1637

Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

^{Jr}
June 27, 2003



ETHAN WHISENANT
PRIMARY EXAMINER